Employee Basic Medical Insurance (UEBMI) claims of Tianjin city from April 2008 to March 2010 were used to compare the patients' outpatient visit, total spending, drug spending, and OOP spending before and after the implementation of the EMP. The intervention group consisted of patients who visit the primary care institution which implemented EMP at least once before and after EMP and did not visit the control primary care institution which did not implement EMP, vice versa for the control group. A difference-in-difference approach was used to estimate the effects adjusting for patients' socio-demographic characteristics and disease severity. Negative binomial regression was used to estimate the outpatient visit and tobit model was used to estimate the cost. **RESULTS:** Totally, 23362 patients from 49 interventional primary care institution and 4148 patients from 42 control institution were involved in the study. The regression results showed that the annual patients' outpatient visits (0.5%, p=0.791) and the visits to primary care institution (0.2%, p=0.951) had no change after implementing EMP compared to the control group. The patient's average total spending (-0.6%, p=0.850), drug spending (1.6%, p=0.703) and OOP spending (0.4%, p=0.883) did not change. The average total spending (2.9%, p=0.443), drug spending (1.9%, p=0.724) and OOP spending (1.2%, p=0.722) in primary care institution was also not changed after implementing EMP. **CONCLUSIONS:** The EMP in Tianjin China was not associated with more outpatient visits in primary care institution and less medical spending, drug spending and OOP spending.

PHP14

IMPACT OF 2014 ESSENTIAL HEALTH BENEFIT BENCHMARK PLANS ON US MANAGED CARE

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OBJECTIVES: Beginning in 2014, the Affordable Care Act requires new health plans to cover essential health benefits (EHB), including pharmaceutical products, according to the state level benchmark plans. The objectives of this analysis were to understand state level variations in design of plans, access to drugs and likely impact on patient choice and health outcomes. **METHODS:** Benchmark plans for the top five states (i.e., FL, IL, NY, TX and CA), covering ~116 million lives, were obtained from the CMS. For each plan, the categories, classes and number of covered drugs was collected and pooled into one database. Analysis was conducted at the entire population level, state-level and for top classes of drugs. The comments from patient groups were reviewed to understand the impact of EHB on patient choice and health outcomes. **RESULTS:** Benchmark plans for the top five states provide coverage of 4215 drugs belonging to 158 classes as defined by USP. While four states (FL, IL, NY and TX) had a similar number of covered drugs (median of 892 drugs), CA had a significantly lower number of covered drugs, amounting to 28% less than the other four states. On average, 10% of the drugs were in the class called "No USP Class", highlighting the limitation of CMS designated USP classification system for the new plans. In CA, FL, IL, NY and TX there were 18, 7, 8, 11 and 8 classes, respectively, for which only 1 was covered. In CA, top 8 classes were identified for which patients had a 75% lower choice than other states, and these included indications such as Anti-Diabetics and Pain medications. **CONCLUSIONS:** Review of new benchmark plans shows some states can have a significantly lower patient choice of therapies. There is a need for new policy measures to ensure that all patients have equal access to new treatments.

PHP15

AN ASSESSMENT OF THE THERAPEUTIC BIOLOGIC PRODUCTS LICENSED BY THE FDA AND THE EMA

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OBJECTIVES: Therapeutic biologic products (BLA) are produced in living cell cultures or through genetic engineering of proteins. The FDA BLA definition excludes allergenics, blood products, cellular and gene therapy, tissue products, and vaccines. This study assessed trends in BLAs licensed by the FDA and the European Medicines Agency (EMA) in the period 1995-2014. **METHODS:** Regulatory information for BLAs was derived from the agencies webpages. We extracted data for BLAs approved before the establishment of the EMA licensing process from the UK Medicines and Healthcare products Regulatory Agency (MHRA). Insulins and some hormones that are approved by the FDA using the drug application system, were excluded from analysis. BLA were classified using the WHO anatomical therapeutic chemical classification. Descriptive statistics and chi-square tests were conducted in the study. **RESULTS:** 115 BLA were licensed by the FDA and the EMA in the period 1995-2014. The FDA licensed 85.2% and the EMA 73.0% of the BLAs (p<0.0001), with 22.6% of the BLAs licensed only by the FDA and 14.8% by the EMA. There were 5 BLA licensed by MHRA and the FDA. The EMA refused to license 4 BLAs. There were 62 BLAs (53.9% of the total) licensed by both agencies. The FDA licensed first 79.0% of the BLAs and the EMA 21.0%. The FDA licensed the BLAs in a median of 181 days before than the EMA. The largest number of BLAs corresponded to antineoplastic and immunomodulating agents (48.7% of BLAs), blood and blood forming organs (13.0%), and alimentary tract and metabolism (9.6%). **CONCLUSIONS:** The study found differences in the number of BLAs licensed by the FDA and the EMA. The FDA approved faster and licensed significantly more BLAs than the EMA. Future research should evaluate the effect in patient outcomes and cost of differences in BLAS availability in US and Europe.

PHP17

THE IMPACT OF NEW DRUG PRICING POLICY ON MARKET COMPETITION AMONG OFF-PATENT DRUGS IN SOUTH KOREA

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OBJECTIVES: This study aims to evaluate the impact of the new pricing policy implemented as of April, 2012 in South Korea on market competition among off-patent drugs since the reform has taken an objective to introduce market competition mechanisms among off-patent drugs. According to the new pricing scheme, prices of brand-name and generic drugs are to be set to the same level after the patent expires. **METHODS:** The data used for this study were extracted from the National Health Insurance Claims database. We established a monthly panel dataset pertaining to pharmaceutical consumption between January 2011 and June 2013 (30 months). Proxies of market competition were considered as dependent variables such as price dispersion, market share of originators and relative ratio of utilization (originator/generics). Independent variables including policy effect, number of generic drugs, vintages of the first generic drugs, month for new generic entry and market value. **RESULTS:** The new pricing policy has resulted in no competition mechanism. Rather the policy shows more favorable to originators than generic drugs. Price dispersion has significantly decreased to 0.92 after the new pricing regulations. Market share of the originators has not significantly changed. However, originator-to-generic utilization ratio significantly increased to 6.12 (p<0.001) after the new policy. This study offers different results to the government's intention. **CONCLUSIONS:** Price competition cannot be successfully achievable unless demand-side measures are combined. To lower prices, the bigger market share should be delivered through demand-side measures such as the reference pricing or compulsory substitution to lowest drugs applied in some European countries.

PHP18

THE ROLE OF COST-EFFECTIVENESS STUDIES IN DRUG PRICING DECISIONS: A CASE REVIEW FROM JORDAN

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OBJECTIVES: To approve a public price for a drug in Jordan, Jordan food and Drug association (JFDA) drug pricing committee ought to review the lowest price in the country of origin, the price of a predefined 13 countries and in KSA. In 2012, the evidence of cost-effectiveness (CE) was required to inform decisions of drug pricing. We sought to assess the role of CE studies in pricing drugs in Jordan. **METHODS:** A retrospective review of all applications submitted to the JFDA between November 2013 to January 2015. **RESULTS:** The committee reviewed a total of 1,608 drug pricing requests. Two hundred four were ricing new drugs, 369 were pricing local and international generics. The remainder was for pricing drugs previously registered in Jordan but renewed periodically as per policy. There was 11 enquires involving the use of CE studies. Applicants failed to correspond adequately to the committee and the committee often reconfirmed the requests more than one time. Median (IQR) of correspondences was 2 (3) times per case. These studies were non-comparative and concerning with establishing clinical efficacy. Median (IQR) ratio of the price proposed by applicants to the price of comparable substitute(s) was 1.7 (1.5). The prices were always negotiated downwards close to the price of the available substitutes. A premium price (i.e. +10% to 20%) was advocated to reward for added benefits such as convenience. **CONCLUSIONS:** The Jordanian pricing policies are comprehensive in responding to most of drug pricing applications. Decisions are straightforward with most comparisons made between drugs having similar clinical profiles. However, where CE evidence required there is no formal decision rules laid down, thus an official set of decision tools is warranted. This would include details of the perspective to be adopted, the comparisons to be made, form of economic evaluation and sources of data.

PHP19

THE DIFFERENCE BETWEEN THE MAXIMUM RETAIL PRICE AND TENDER PRICE: A COMPARATIVE STUDY ON BRANDNAME AND GENERIC DRUGS

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OBJECTIVES: To compare the difference between the maximum retail price and tender price of brandname and generic drugs. **METHODS:** A large database analysis was used. The database was formed by merging two sub-databases, one was the tender prices of 94 antimicrobial drugs and circulatory system drugs collected from the centralized tendering of drug purchases across all the provinces(autonomous regions, municipality directly under the central government) of mainland China over the period of 2005-2013, the other was the corresponding maximum retail prices issued by the National Development and Reform Commission of China. The percentage differences between the maximum retail price and tender price (provincial average) was then calculated by year for antimicrobial drugs and circulatory system drugs, respectively. The generic-brandname ratio of the concerned percentage differences was also calculated. **RESULTS:** The percentage difference between maximum retail price and tender price for generic drugs was large, while the corresponding difference in brandname drugs was much smaller. The generic-brandname ratio of the concerned percentage differences increased from 1.7 in 2005 to 5.7 in 2013, except a mild decrease in 2009 and a moderate decrease in 2012. **CONCLUSIONS:** It may be the time to lift price control on drugs in China since the maximum retail price issued by the national government was too high as compared with tender price to exert effect on generic drugs, while for brandname drugs the maximum retail price was too close to tender price, which also consequentially diluted the significance of maximum retail price. **KEYWORDS:** Maximum retail price; Tender price; Price reform; large database analysis.

PHP20

ANALYSIS OF THE DRUG PRICE REVIEWS PERFORMED BY THE CANADIAN PATENTED MEDICINE PRICES REVIEW BOARD (1998-2014)

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OBJECTIVES: Canada has established Patented Medicine Prices Review Board (PMPRB) in 1987 with the objective of regulating prices of patented medicines sold in Canada to ensure prices are not excessive. When drugs' prices meet the guidelines, they will be accepted; otherwise, the sponsor company will decrease them. The

objective of this study was to assess the characteristics of the reviews performed by the PMPRB in the period of 1998 to 2014. **METHODS:** Data for all reviews performed by the PMPRB in the period 1998 to 2014 were derived from the PMPRB webpage. Descriptive analysis, and trend analysis were conducted. **RESULTS:** PMPRB reviewed a total of 1457 formulations/strengths corresponding to 689 active ingredients and combinations in the study period. Seventy percent of PMPRB prices were within the guidelines and accepted. Two percent of the prices exceeded the guidelines but did not trigger the criteria for commencing an investigation; however, the patentee is expected to decrease the price. Three percent of the National Average Transaction Price exceeded the Maximum Average Potential Price, which triggered the investigation criteria and the drug was reported "Under Investigation". Four percent of the drug prices investigated were not excessive. One and half percent of the drug prices were considered excessive, and by getting to this conclusion two percent of patentees submitted a Voluntary Compliance Undertaking (VCU). Finally one and half percent of patentees did not submit a VCU and PMPRB decided that a patented medicine was sold at an excessive price in any market in Canada, and the PMPRB issued a Notice of Hearing. Drug prices that were within guidelines ranged from92.6% (2001 to 2004) to 95.2% (2005 to 2009) respectively. However, it decreased to 69.8%in 2010-2014. **CONCLUSIONS:** The majority of the reviews performed by the PMPRB concluded that the prices were not excessive.

PHP21

CHANGES OF THE HUNGARIAN HEALTH INSURANCE PHARMACEUTICAL BUDGET BETWEEN 2007-2013

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OBJECTIVES: At the end of 2006, there was an important reform in the Hungarian pharmaceutical market, including serious changes in the health insurance reimbursement of medicines. The aim of our study is to analyze the changes in the Hungarian health insurance pharmaceutical budget between 2007-2013. **METHODS:** Data were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency in Hungary. We analyzed the changes of the health insurance pharmaceutical budget between 2007-2013. Results are given in Hungarian Forint (HUF) and US dollars (USD). The annual average currency exchange rates were applied according to the data of the Central Bank of Hungary. **RESULTS:** The Hungarian pharmaceutical budget was 323.6 (2007), 325.7 (2008), 343.2 (2009), 357.2 (2010), 376.9 (2011), 315.1 (2012) and 280.0 (2013) billion HUF. The average annual exchange rate between Hungarian Forint and US dollar was 183.83 (2007), 171.80 (2008), 202.26 (2009), 208.15 (2010), 200.94 (2011), 225.37 (2012) and 223.70 (2013), which means that Hungarian Forint significantly weakened compared to USD. After the changes in currency exchange rate, the Hungarian pharmaceutical budget measured by US dollars was 1.76 (2007), 1.90 (2008), 1.70 (2009), 1.72 (2010), 1.88 (2011), 1.40 (2012) and 1.25 (2013) billion USD. The decrease of pharma reimbursement budget from 2011 to 2013 was more significant in USD dollar (33.3 %) than in Hungarian Forint (25.7 %) due to the weakened Hungarian currency. **CONCLUSIONS:** Due to the reform of the whole Hungarian pharmaceutical market, the Hungarian health insurance pharmaceutical budget significantly changed between 2007-2013. This change was more remarkable in USD as the Hungarian currency weakened compared USD during the world economic crisis.

PHP22

EFFECT OF THE U.S.-PERU FREE TRADE AGREEMENT ON PERUVIAN NEW DRUG POLICIES AND THE REGISTRATION OF PHARMACEUTICAL PRODUCTS

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OBJECTIVES: One controversial issue surrounding the Free Trade Agreement (FTA) is patent protection and access to medicines. The FTA necessitated changes in Peruvian legislation to meet requirements of the treaty. This study evaluated the impact of the FTA on number of brand and generic pharmaceuticals registered before and after the agreement and implementation of the new legislation of 2009. **METHODS:** Data from 2005 to 2013 were extracted from the database provided by the Peruvian drug regulatory authority, DIGEMID. The frequency and proportion of brand and generic products registered for the first time at DIGEMID were determined using the variable 'authorization date of first registration'. Re-registered products were determined using the 'authorization and expiration date' of registration. Products awaiting registration were determined by the variable 'status of application'. Chi-square was used to assess differences in proportions. **RESULTS:** A total of 30,201 pharmaceutical and 913 biologics products with a unique registration number were evaluated. The proportion of new registrations was 74% (n=1789) for brand and 26% (n=621) for generic products in 2005; and 80% (n=455) for brand and 20% (n=114) for generic products in 2013 with a decrease of 1,841 (76%) products after legislation. The proportion of re-registrations was 66% (n=714) for brand and 34% (n=361) for generic products in 2005 with the same proportions in 2013 but different frequencies (58 brand and 30 generic) with a decrease of 987 (92%) products after legislation. There were statistically significant differences between brand and generic products before and after the legislation. The proportion of awaiting registrations was 3 times greater for brand than for generic products from 2009 to 2013. **CONCLUSIONS:** Registration of brand products was greater than generic products before and after the FTA and new legislation. The frequency of new registrations and re-registrations decreased after 2009 but increased for products awaiting registration.

PHP23

THE CHARACTERISTICS OF PHARMACY AND THERAPEUTIC COMMITTEES IN SAUDI HOSPITALS

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OBJECTIVES: The Pharmacy and Therapeutics Committee (P&TC) is a policy recommending and enforcing body which oversees the adoption of effective formulary system within the health care organization, the aim of the study is to explore the characteristics of P& TC in tertiary and secondary hospitals in Riyadh city, Saudi Arabia. **METHODS:** A cross-sectional survey targeted hospital pharmacy mangers in Riyadh city in 2014. The survey gathered information about P&TC organizational, communicational and functional characteristics. **RESULTS:** Of 30 hospital pharmacies, 23 (76.6%) pharmacy managers responded, 21(70%) hospitals met the inclusion criteria, 15 (71.4%) are governmental and 6 (28.6%) are private hospitals. Of 21 hospitals, 20 (95.2%) have P&T Committee. 15 (71.4%) committees have all required written policies and procedures that govern the committee business. The average total number of the P&T committee members is 13.5 (SD=5), and dominated by physicians, pharmacists, and nurses (6.9 (SD=3.4), 2.7(SD=1.2), and 1.4(SD=0.8)) respectively. 89.5% of these committees are chaired by physicians and 100% of them are coordinated by the pharmacists. Only 9 (45%) of the committees distribute the meeting agenda to their members 6 days or more before the meeting date. The average number of meetings is 12 (SD=6) meeting per year, drug availability, formulary change updates, drug safety related issues were frequently discussed in each meeting of 11(55%) hospital P&T committees. Formulary non adherence is less frequently, and prescribing guidelines is the least frequent. The average number of drugs deleted or added to the formulary are 6.3(SD=5.9), 19.2 (SD=18.9) drug per year, respectively. **CONCLUSIONS:** Adopting P&T Committee in Saudi governmental hospitals is a common practice, however, it considered in early stage in private hospitals and more likely to be contributed to the accreditation requirements, therefore, more study to be done to study the quality of the committees in private hospital to ensure the effectiveness of formulary system.

PHP24

PRINCIPLES OF POLICY FRAMEWORK IN THE PHARMACEUTICAL WHOLESALE AND RETAIL SYSTEM IN LOWER INCOME EUROPEAN COUNTRIES

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OBJECTIVES: To determine the influencing factors and main principles of regulatory and policy framework in the pharmaceutical wholesale and retail system to identify good practices for adaptation in Central Eastern European (CEE) countries. **METHODS:** A comprehensive literature review in the scientific and grey literature and a series of expert interviews were conducted to identify influencing factors in three major categories: general political, business economic and health policy principles. **RESULTS:** Regulatory and policy framework related to the pharmaceutical wholesale and retail system is influenced by multiple stakeholders with different interest. Health policy demands timely access to high quality medicines to maximise health gain for the population with respect to equity. Budget constraints necessitate public need for a sustainable and efficient pharmaceutical distribution channel. To overcome these constraints, pharmaceutical wholesalers and pharmacies have to improve operational efficiency by taking into account economies of scale/scope; or positive synergies of horizontal and vertical integration. According to general political objectives policy makers may choose from 1) regulated vs. liberalised system, 2) with monopolistic vs. competing wholesalers and community pharmacies 3) with national vs. international, and 4) public vs. private ownership. Pharmacists may consider the provision of advanced health care services besides the traditional logistic activities to intensify professional influence on health policies. **CONCLUSIONS:** Evidence base of policy and regulatory framework related to pharmaceutical trade can be improved based on comprehensive review of scientific evidence on major principles to harmonise different objectives of stakeholders. However, publications with relevance to CEE and in general lower income countries are very limited.

PHP25

ORPHAN AND ULTRA-ORPHAN TECHNOLOGIES IN THE NEW ERA OF PAYMENT REFORM: UNITED STATES PAYER PERCEPTIONS

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OBJECTIVES: To understand United States (US) payer perceptions and challenges in the evaluation of emerging health technologies with orphan and ultra-orphan designations. **METHODS:** In-depth, qualitative, one-on-one interviews were conducted with US payer decision makers from the RTI Health Solutions US Commercial Payer Advisory Panel. **RESULTS:** In the US, patient access to orphan and ultra-orphan technologies is seldom denied due to the rarity of the diseases, unmet needs, and lack of alternative treatments. Payers identify the biggest challenges as lack of clinical and comparative efficacy data and pressures from advocacy groups, patients, and prescribers to fund the ever-increasing numbers of orphan and ultra-orphan technologies, which are often very expensive and have limited clinical evidence. Payers estimated that spending for orphan and ultra-orphan technologies will increase significantly in the next 5 years, leading to concerns over future funding and budgets. Payers were interested in data that could have an impact on costs, cost offsets, resource utilization, readmissions, and real-world outcomes in their settings and patient/member populations. Payers wanted to see better-defined patient populations and unmet needs accompanied by well-defined treatment courses (e.g., when to stop treatment). Benefits of new technologies may not be captured in traditional health economic analyses, thus increasing uncertainty. Bridging the clinical evidence with other robust data will be critical, because payers will be passing on more risk to patients and prescribers in an effort to manage budget constraints. **CONCLUSIONS:** Payers are seeking more value-based information to better inform decision making in the evaluation of new orphan and ultra-orphan technologies. The challenge to payers lies with the value of the new technology and who is judging that value. Rising costs of orphan and ultra-orphan technologies will have more impact on market access in the future; over time there will be increasing resistance to high prices.